POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M92-9 (rev.) 19 September 2000

MANUAL TRANSMITTAL SHEET

SUBJECT: Administration of Sedation

1. Explanation of Material Transmitted: This issuance transmits the revised policy of the Clinical Center on the procedures to be followed by non-anesthesiologists before, during and after the administration of medication to either adult or pediatric patients for conscious or deep sedation or analgesia. This policy was approved by the Medical Executive Committee on 20 June 2000. On 19 September 2000, the attached Sedation Worksheet, NIH form 546-3, was removed from the policy. The form has been revised and is available from the CC Forms Office.

2. Material Superseded: MAS No. M92-9, dated 21 June 2000

3. Filing Instructions: "Other" section

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Physicians, Dentists and Other Practitioners Participating in Patient Care

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SUBJECT: Administration of Sedation

PURPOSE

To ensure the safety of all patients receiving either conscious or deep sedation (defined below) provided by non-anesthesiologists for a medical procedure.

BACKGROUND

At the Clinical Center (CC), sedation is administered to patients in many locations by non-anesthesiologists. This CC policy represents the minimum standards to be adhered to in any location where sedation is administered by non-anesthesiologists to ensure that the same standards of care are followed throughout the Clinical Center.

DEFINITIONS

Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to rescue patients whose level of sedation becomes deeper than initially intended. Individuals administering Moderate Sedation/Analgesia (Conscious Sedation) should be able to rescue patients who enter a state of Deep Sedation/Analgesia, while those administering Deep Sedation/Analgesia should be able to rescue patients who enter a state of General Anesthesia.

Continuum of Depth of Sedation
Definition of General Anesthesia
and Levels of Sedation/Analgesia

	Minimal Sedation (Anxiolysis)	Moderate Sedation/Analgesia (Conscious Sedation)	Deep Sedation/Analgesia	General Anesthesia
Responsiveness	Normal response to verbal stimulation	Purposeful* response to verbal or tactile stimulation	Purposeful* response following repeated or painful stimulation	Unarousable even with painful stimulus
Airway	Unaffected	No intervention required	Intervention may be required	Intervention often required
Spontaneous Ventilation	Unaffected	Adequate	May be inadequate	Frequently inadequate
Cardiovascular Function	Unaffected	Usually maintained	Usually maintained	May be impaired

Minimal Sedation (Anxiolysis): a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

Moderate Sedation/Analgesia (Conscious Sedation): a drug-induced depression of consciousness during which patients respond purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Deep Sedation/Analgesia: a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully* following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

General Anesthesia: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

* Reflex withdrawal from a painful stimulus is NOT considered a purposeful response.

POLICY

I. The administration of sedation will be under the constant supervision of a healthcare provider (physician, dentist, physician's assistant, or nurse practitioner) who is privileged to administer conscious or deep sedation. To be privileged to direct the administration of sedation, a healthcare provider must have current ACLS or PALS certification and must have completed the Clinical Center Sedation Credentialing Course.

II. All patients receiving sedation will be thoroughly evaluated before the administration of sedation and will be appropriately monitored immediately before, during, and after the procedure for which sedation is administered; this will be documented on the Sedation Worksheet (NIH form 546-3, available from the CC Forms Office, 496-0827, 10/1N205).

III. Pediatric patients less than 10 years old who will be sedated for any procedure should be assessed by their primary team for the need of an anesthesia consultation. The primary team should consider an anesthesia consultation unless the patient has previously demonstrated the ability to have these procedures without sedation.

IV. This policy does not apply to the following clinical circumstances in which sedatives/analgesics may be administered:

a) a patient whose medical condition requires analgesic agents for the control of pain.

b) a patient who requires sedation to tolerate mechanical ventilation.

c) a patient who requires sedation secondary to an acute psychiatric disturbance which may result in potentially harmful behavior.

Exception for Minimal Sedation (Anxiolysis)

This policy does not apply to patients receiving a single dose of an oral medication by itself (i.e., not in combination with any other sedative, hypnotic or analgesic) given in a dose anticipated to provide anxiolysis while maintaining control of protective airway reflexes. However, if there is a reasonable risk of loss of protective airway reflexes due to underlying patient condition or medications or if additional medications are administered, this policy applies.

In addition, patients who receive pre-operative or pre-procedure sedative medication (premedication) by any route must be

monitored with pulse oximetry continuously from the time the medicine takes effect. The Sedation Worksheet is not designed to be used for these patients during this period.

Medications

I. The following medications are approved for the provision of Moderate (Conscious Sedation) or Deep Sedation/Analgesia in the Clinical Center under the supervision of healthcare providers with privileges to provide sedation:

a) Benzodiazepines

Midazolam, Diazepam, Lorazepam

b) Opioids

Fentanyl, Morphine, Meperidine

c) Other agents

Diphenhydramine

II. The following medication has a narrow therapeutic window and is approved for the provision of Deep Sedation/Analgesia only under the supervision of healthcare providers with anesthesia privileges or in an intensive care unit:

Ketamine

III. The following medications are approved for use by healthcare providers with anesthesia privileges in any patient or by other healthcare providers only in patients on mechanically assisted ventilation with an endotracheal tube or tracheostomy:

a) Induction agents

Propofol

Barbiturates (e.g., sodium pentothal, methohexital, etc.)

Etomidate*

b) Potent narcotics

Remifentanil

Sufentanil

c) Inhalational agents (requires waste gas scavenging)

Halogenated agents (e.g., isoflurane, halothane, desflurane, sevoflurane)

* May be used to induce adrenal suppression without a controlled airway but only in an intensive care unit.

d) Neuromuscular blocking agents

Succinylcholine	Mivacurium
Cisatracurium	Rapacuronium
Rocuronium	Pancuronium
Vecuronium	Doxacurium

Anesthetizing locations

Any patient care area in the Clinical Center where procedures are performed on patients or normal volunteers that require sedation/analgesia is considered an anesthetizing location. These sites must have the requisite monitoring capability, resuscitation equipment, and staffing as specified in this policy to be considered an approved anesthetizing location for Moderate (Conscious Sedation) or Deep Sedation/Analgesia. (See below)

In addition, the anesthetizing location must have sufficient space to accommodate all necessary equipment, enough electrical outlets for this equipment (including outlets clearly labeled and connected to an emergency power supply), adequate illumination for the procedure, and a reliable means of two-way communication to request assistance.

GUIDELINES

In high risk adult patients, American Society of Anesthesiologists (ASA) Physical Classification III or above (see attachment A), the administration of sedation should ideally be directed by an anesthesiologist or an intensivist. A formal request for anesthesia/critical care services or consultation should be obtained whenever the primary team feels it is warranted to ensure safe completion of the procedure.

All children receiving sedation must be supervised by a healthcare provider with CC sedation privileges who is either a pediatrician, has PALS certification, or has experience managing pediatric sedation because the level of sedation in children is more variable than in adults. In addition, a pediatric patient's airway may be more easily compromised. Because of these factors, pediatric patients should always be monitored as if they were deeply sedated even when receiving oral sedation, except as noted above for anxiolysis.

PROCEDURES

Before Sedation

A responsible adult must accompany pediatric outpatients to and from the Clinical Center. Adult outpatients may arrive without an escort but must leave with a responsible adult.

I. A physical examination appropriate to the patient and the procedure, must be performed by a physician, dentist, physician's assistant, or nurse practitioner. If a physical examination was completed within the preceding 30 days, interim changes, or lack thereof, must be documented.

II. A pre-sedation evaluation must be performed and documented in the Sedation Worksheet. This evaluation will consist of a patient interview, assessment and review of the medical record to obtain the following information:

a) Past medical/surgical history (including previous exposure to sedatives/analgesics)

b) Allergies

c) Current medications

d) Weight and age

e) Vital signs (heart rate, blood pressure, respiratory rate, temperature, and oxygen saturation)

f) Airway evaluation (ability to open mouth, flex/extend neck and relative size of jaw/tongue)

g) Pertinent laboratory data

h) ASA physical status (See attachment A)

III. NPO status will be confirmed. (See attachment B)

IV. The following monitoring and resuscitation equipment (appropriately sized to the patient) must be available at the anesthetizing location and the recovery area.

a) Blood pressure monitor

b) Pulse oximeter

c) Wall source oxygen delivery system

d) Wall source suction apparatus

e) Intravenous access equipment

f) Medications (sedatives, analgesics, antagonists and emergency drugs)

g) Bag-valve-mask ventilation equipment

V. Sedated patients transported to or from a procedure area will be monitored during transport by visual observation and pulse oximetry. All staff transporting sedated patients must be certified in basic life support and know how to activate the "code blue" system. A resuscitation pocket mask will accompany the patient. If the standard resuscitation pocket mask is too large for the patient, a properly sized bag-valve-mask must be available.

During Sedation

I. A pre-sedation set of vital signs and fitness assessment (confirming the patient is a suitable candidate for sedation) must be recorded immediately prior to the procedure.

II. The healthcare provider supervising the administration of sedation must remain with the patient for the entire procedure.

III. The individual monitoring the sedated patient (i.e., assessing the airway, recording vital signs) must have no other assigned responsibilities during the procedure. This individual must also have basic life support certification.

a) During Moderate Sedation/Analgesia (Conscious Sedation), the individual monitoring the sedated patient must remain with the patient for the entire procedure (with the exception of short interruptible tasks).

b) During Deep Sedation/Analgesia, the individual monitoring the sedated patient must remain with the patient for the entire procedure without exception.

IV. The following minimum data will be recorded every 5 minutes on the Sedation Worksheet:

a) Heart rate

b) Blood pressure

c) Respiratory rate

d) Oxygen saturation

e) Level of consciousness

V. Medication orders (dosage, time and route of administration) will be written or entered into the MIS.

VI. Excessive sedation may result in airway obstruction, decreased oxygenation, inadequate respirations, or hemodynamic instability. Healthcare providers shall use appropriate measures to restore satisfactory respiratory and cardiovascular function.

Recovery

A recovery area must be identified prior to any sedation procedure. This area must have the same monitoring capability as the procedure site, and it must have nursing personnel certified in basic life support to monitor the patient continuously (by direct visualization) until recovery or discharge criteria are met. Monitoring will be recorded a minimum of every 15 minutes and will consist of heart rate, oxygen saturation, blood pressure (or capillary refill in pediatric patients), respiratory rate, and level of consciousness.

Discharge Criteria

I. Inpatients[*] may be discharged from the recovery area when all of the following criteria have been met and documented:

a) Post sedation score is at least nine out of ten.
    1. Patient is able to move their extremeties.
    2. Respiratory rate and effort have returned to baseline.
    3. Blood pressure is within 20% of baseline.
    4. Patient has returned to pre-procedure level of consciousness.
    5. Oxygen saturation is greater than 94% on room air or supplemental oxygen requirement is at baseline level.

b) Airway reflexes are intact.

c) Bleeding is controlled.

d) Hydration is adequate.

e) Patient has minimal or no nausea and no emesis for at least 20 minutes.

II. Outpatients[**] must also meet the following additional criteria:

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[*] Inpatients may bypass the recovery area and go directly back to their patient unit at the completion of the procedure if all the above criteria are met and documented on the Sedation Worksheet (NIH 546-3).

[**]All outpatients must go to a designated recovery area following any procedure requiring Moderate (Conscious) Sedation or Deep Sedation/Analgesia.

a) A responsible adult demonstrates knowledge of "post operative instructions."

b) The patient tolerates oral intake (clear liquids).

c) If appropriate, a discharge or transfer order will be entered into the MIS by the responsible health care provider.

III. Recovery from sedation to pre-sedation baseline must be documented. The privileged provider responsible for the administration of sedation (or another privileged sedation provider identified to the recovery personnel) must remain available in the Clinical Center until all applicable discharge criteria are met. When the recovery nurse has determined that discharge criteria are met, this nurse may discharge the patient.

REFERENCES

Guidelines for Monitoring Patients During and After Sedation. American Academy of Pediatrics. 1992.

Sedation/Analgesia for Diagnostic/Therapeutic Procedures in Children. Children's National Medical Center, Washington, DC. 1994.

Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists. A report by the American Society of Anesthesiologists Task Force on Sedation and Analgesia by Non-Anesthesiologists. Anesthesiology 84: 459-471. 1996.

Position Statement on the Role of Registered Nurses in the Management of Patient's Receiving IV Conscious Sedation for Short Term Therapeutic, Diagnostic or Surgical Procedure. American Association of Critical-Care Nurses. 1991.

Post Anesthesia Care Unit. Standards for Nursing Care. Washington Hospital Center, Washington DC. 1993.

Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia. American Society of Anesthesiologists House of Delegates. October 13, 1999.

Modifications to the Postanesthesia Score for Use in Ambulatory Surgery. Journal of PeriAnesthesia Nursing 13: 148-155. 1998.

ATTACHMENT A

American Society of Anesthesiologists (ASA) Physical Status Classification System

I. A normal healthy patient

II. A patient with mild systemic disease

III. A patient with severe systemic disease

IV. A patient with severe systemic disease that is a constant threat to life

V. A moribund patient who is not expected to survive without the operation

VI. A declared brain-dead patient whose organs are being removed for donor purposes

ATTACHMENT B

NPO GUIDELINES FOR PATIENTS RECEIVING SEDATION

0 - 6 Months	No milk or solids for four hours before scheduled procedure
6 - 36 Months	No milk or solids for six hours before scheduled procedure
> 36 Months	No milk or solids for eight hours before scheduled procedure

Clear liquids are acceptable for all ages until two to three hours before scheduled procedure.